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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/615,703

07/09/2003

Stephen J. Benkovic

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12/05/2006

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,703

Applicant(s)

BENKOVIC ET AL.

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,8,15,18,19,23-40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9-14,16,17,20-22,41,42 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 06/02/2006 and 09/20/2006 are acknowledged and entered.

2. Claims 1-44 were pending. No claims were amended, added, and/or cancelled.

Therefore, claims 1-44 are currently pending.

Election/Restrictions

3. Applicant's election with traverse of Group II (Claims 12-22 and 41-44) in the reply filed on 06/02/2006 is acknowledged.

The traversal is on the ground(s) that [1] Group I (Claims 1-11), Group II (Claims 12-22 and 41-44), and Group III (Claims 23-40) represent "related" subject matter and [2] there would be no search burden on the Examiner to conduct a search of the entire claim set.

This is found persuasive with regard to Group I (Claims 1-11) and Group II (Claims 12-22 and 41-44), and as a result Group I is rejoined with Group II. Therefore, Group II is claims 1-22 and 41-44.

This is not found persuasive with regard to Group III (Claims 23-40) and Group II (Claims 1-22 and 41-44) because [1] First, the Examiner notes that the mere presence of any alleged overlapping subject matter would not constitute a coextensive search because each Group would have to be searched to its full extent and not just to the extent of any overlapping subject matter, which would, as a practical matter, encompass non-overlapping subject matter and hence result in a non-coextensive search. [2] In addition, as stated in the Restriction Requirement dated

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02/24/2006, these inventions (Groups II and III) have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and/or products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden for the Office.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 23-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a *nonelected invention*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/02/2006.

5. Applicant has elected the following species for the elected invention (Claims 1-22 and 41-44) in the reply filed on 06/02/2006 and 09/20/2006:

- a. For the single specific species of 'type' of DNA methyltransferase activity, applicant elected inhibiting enzyme activity of claim 14.
- b. For the single specific species of microbe, applicant elected "*the species 'helicobacter' described in claim 21 as an example of a gram-negative bacterium as described in claim 20*".

Applicants have identified claims 12, 13, 14, 16, 17, 20, 21, 22, 41, 42, and 44 as reading on the elected species, i.e., "inhibiting enzyme activity" as described in claim 14 and the species *helicobacter* as described in claim 21. In addition, since Group I (Claims 1-11) is rejoined with

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the elected Group II as indicated above in paragraph 3, claims 1-3, 5, 6, and 9-11 are claims that would read on the elected species (a-b) above.

6. Claims 4, 7, 8, 15, 18, 19, and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/02/2006 and 09/20/2006.

7. Claims 1-3, 5, 6, 9-14, 16, 17, 20, 21, 22, 41, 42, and 44 are under consideration in this Office Action.

Priority

8. This instant application is a CIP of three applications, which are 09/996,420 filed 11/29/2001, 09/578,991 filed 05/25/2000, and 09/296,137 filed 03/16/1999. 09/578,991 claims benefit to three provisional applications, which are 60/135,870 filed 05/25/1999, 60/154,582 filed 09/17/1999, and 60/174,256 filed 01/03/2000. 09/296,137 is a 371 of PCT/US97/16,593 filed 09/17/1997, which claims benefit to 60/020,089 filed 09/19/1996.

However, only the limitations of '*A method for treating an animal against a microbe-induced disease*' of claims 1-3, 5, 6, 9-14, 16, 17, 20, 21, 22, 41, 42, and 44 are granted the benefit of priority under 35 U.S.C. 120 for 09/996,420 and 09/578,991, because the limitations of '*A method for treating an animal against a microbe-induced disease*' are directed to subject matter not adequately disclosed under 35 USC 112, first paragraph, in either the parent

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application, i.e. 09/296,137, nor the PCT international application, i.e. PCT/US97/16,593. *In a continuation-in-part application, only claims directed solely subject matter adequately disclosed under 35 USC 112, first paragraph in the parent application is entitled to the benefit of the filing date of the parent application.* In addition, the limitations of '*A method for treating an animal against a microbe-induced disease*' of claims 1-3, 5, 6, 9-11, 12, 13, 14, 16, 17, 20, 21, 22, 41, 42, and 44 are not granted the benefit of priority under 35 U.S.C. 119(e) for 60/135,870, 60/154,582, 60/174,256, and 60/020,089, because the limitations of '*A method for treating an animal against a microbe-induced disease*' are directed to subject matter not adequately disclosed under 35 USC 112, first paragraph, in these four provisional applications. Accordingly, the limitations of '*A method for treating an animal against a microbe-induced disease*' of claims 1-3, 5, 6, 9-11, 12, 13, 14, 16, 17, 20, 21, 22, 41, 42, and 44 are only granted the effective filing date of 05/25/2000.

Furthermore, the limitations of '*A method for protecting an animal against a microbe-induced disease*' of claims 1-3, 5, 6, 9-14, 16, 17, 20, 21, and 22 are entitled only to the filing date of the continuation-in-part application, i.e. 07/09/2003, because the limitations of '*A method for protecting an animal against a microbe-induced disease*' are directed to subject matter not adequately disclosed under 35 USC 112, first paragraph, in either the parent applications, i.e. 09/996,420, 09/578,991, and 09/296,137, nor the PCT international application, i.e. PCT/US97/16,593. In addition, the limitations of '*Acinetobacter species; Brucella species; Bordetella species; Shigella species; Salmonella species; Klebsiella species; Enterobacter species; Pasteurella species; Streptobacillus species; Spirochetal species; Rhizobium species; Enterococcus faecalis; Enterococcus faecium; Acinetobacter baumannii; and Francisella*

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tularensis' of claims 10, 11, 21, 22, and 42 are entitled only to the filing date of the continuation-in-part application, i.e. 07/09/2003, because these limitations are directed to subject matter not adequately disclosed under 35 USC 112, first paragraph, in either the parent applications, i.e. 09/996,420, 09/578,991, and 09/296,137, nor the PCT international application, i.e. PCT/US97/16,593. *In a continuation-in-part application, only claims directed solely subject matter adequately disclosed under 35 USC 112, first paragraph in the parent application is entitled to the benefit of the filing date of the parent application.*

Oath/Declaration

9. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See alterations made for inventor Irene Lee.

Specification

10. The disclosure is objected to because of the following informalities:

A. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/296,137 is a 371 of PCT/US97/16,593 filed 09/17/1997. However, the specific reference to the earlier filed application must be made in the instant application, i.e. a reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the

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filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. *Also, the current status of all nonprovisional parent applications referenced should be included.* Here, the instant specification does not have *the current status* of the Application No. 09/296,137, which is now US Patent 6,413,751 B1.

Appropriate correction is required.

Claim Objections

11. Claim 42 is objected to because of the following informalities: In claim 42, the acronym “*spp.*” is not defined in the claims so that those who are ordinary skills in the art would know applicant intended meaning. It should be define on its first appearance. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 12-14, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasseur et al. (*Antimicrob. Agents Chemother.*, 4/1993, 37(4), pgs. 889-892) alone or as evidence by Barbés et al. (*FEMS Microbiology Letters*, 6/1990, 69(3)).

For *claims 1, 12 and 41*, Brasseur et al. disclose a curative therapy (refers to instant claimed method of treating) and preventative therapy (refers to instant claimed method of treating) using sinefungin for immunosuppressed adult rats that are infected with *Cryptosporidium parvum* (refers to a microbe-induced disease)(see e.g. Abstract; pg. 889, left col., lines 15-20; pg. 890, left col., lines 9-22; pg. 890, right col., lines 3-26). The methods comprise administering to the immunosuppressed adult rats that are infected with *Cryptosporidium parvum* a therapeutic effective dose of sinefungin (see e.g. pg. 890, left col., lines 9-22; pg. 890, right col., lines 3-26; pg. 889, Table 1; pg. 890, Tables 2 and 3; pg. 891, Table 4). Sinefungin is a known antibiotic wherein it inhibits the methyltransferase activity of parasites (see e.g. pg. 891, left col., lines 14-28).

For *claims 1-3, 13, and 14*, although Brasseur et al. does not disclose that sinefungin inhibits the DNA adenine methyltransferase activity of parasites this property of sinefungin is well known in the art as evidence by Barbés et al., pgs. 239-243)(see e.g. pg. 239, left col., lines 3-16; pg. 240, left col., lines 6-9; pg. 241, left col., line 31 thru right col., line 33).

Therefore, the method of Brasseur et al. does anticipate the instant claimed invention.

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14. Claims 1-3, 6, 9-14, 17, 20, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Heithoff et al. (*Science*, 05/07/1999, 284(5416), pgs. 967-970).

For *claims 1-3, and 12-14*, the term "*or*" of instant claims 1 and 12 implied that it is an alternative, i.e. the method claimed in instant claims 1 and 12 is either a method of treating or a method of protecting. Here, the method claimed in instant claims 1 and 12 is interpreted as a method of protecting.

Heithoff et al. disclose DNA adenine methylase (Dam⁻) mutants and methods of using the Dam⁻ mutants (see e.g. Abstract; pg. 968, 1st col., line 5 thru 3rd col., line 27; pg. 969, 3rd col., lines 10-31). One method comprises the step of immunizing mice with a live attenuated vaccine (refers to instant claimed method step of administering of claim 12) containing Dam⁻ mutants, which inhibit DNA adenine methylation (refers to instant claimed method step of inhibiting of claim 1)(see e.g. pg. 969, 3rd col., lines 10-31; pg. 969, Table 2). This method anticipated the instant claimed method of instant claims 1 and 12, i.e. the method of protecting.

For *claims 6, 9-11, 17, and 21-22*, Heithoff et al. disclose that the vaccine protect the mice from *Salmonella* infection (refers to instant claimed microbe-induced disease)(see e.g. pg. 969, 3rd col., lines 10-31; pg. 969, Table 2).

Therefore, the method of Heithoff et al. does anticipate the instant claimed invention.

15. Claims 1-3, 5, 6, 9-14, 16, 17, 20, 21, 22, 41, 42, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Mahan et al. (US Patent 7,026,155 B2; *effective filing date of 02/02/1999*).

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For *claims 1-3, 12-14, and 41*, Mahan et al. disclose a composition and methods of making and using the composition that renders the bacteria non-pathogenic (see e.g. Abstract; col. 1, lines 29-37; col. 10, lines 5-15; col. 10, lines 49-64). The methods include the method of treating an individual infected with a pathogenic bacteria (refers to instant claimed method of treating of claims 1, 2, and 41)(see e.g. col. 10, lines 49-52; col. 18, line 60 thru col. 19, line 5; col. 35, lines 19-34 and 44-67) and the method of using an immunogenic composition for eliciting an immune response in an individual against a pathogenic bacteria (refers to instant claimed method of protecting of claims 1 and 2)(see e.g. col. 10, lines 53-64; col. 35, lines 35-43). The method of treating comprises the step of administering to an individual a composition that alter the expression of or inhibit the activity of DNA adenine methylases (refers to instant claimed method step of inhibiting of claim 1; instant claimed method step of administering step of claims 12 and 41; and instant claims 2, 3, 13, and 14)(see e.g. col. 10, lines 49-52; col. 18, line 60 thru col. 19, line 5; col. 35, lines 19-34 and 44-67). The method of using an immunogenic composition for eliciting an immune response in an individual against pathogenic bacteria comprises the step of administering to an individual a composition that alter the expression of or inhibit the activity of DNA adenine methylases (refers to instant claimed method step of administering step of claims 1 and 12)(see e.g. col. 10, lines 53-64; col. 35, lines 35-43). The composition comprises a pharmaceutical acceptable excipient and an agent that alters the expression of or inhibits the activity of DNA adenine methylases (see e.g. col. 26, lines 27-46; col. 36, lines 19-48).

For *claims 5, 16 and 44*, Mahan et al. disclose that the individual are human (see e.g. col. 19, lines 6-15).

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For *claims 6, 9-11, 17, 20-22, and 42*, Mahan et al. disclose that the pathogenic bacteria include *Escherichia*, *Vibrio*, *Yersinia*, *Salmonella*, and *Helicobacter pylori* (see e.g. col. 18, lines 32-38, col. 19, lines 35-47; col. 25, line 26 thru col. 26, line 26).

Therefore, the methods of Mahan et al. do anticipate the instant claimed invention.

Conclusion

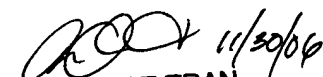
16. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas (Doug) Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
November 27, 2006


MY-CHAU T. TRAN
PATENT EXAMINER